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Applicant: Virtanen
Group Art Unit No. Unknown
Examiner: Unknown

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to the examination of this Divisional application, please amend the application as follows:

IN THE CLAIMS

Please examine following new claims:

34. An assay system for detecting the presence of an analyte comprising:

a wave guide having a radiation inlet and a radiation outlet, said wave guide including a radiation transmissive body of said disk which extends between said inlet and said outlet;

a radiation source that provides radiation of a given intensity to said wave guide inlet, a portion of said radiation being transmitted radially through said body from said inlet to said outlet and a portion of said radiation escaping through said exterior surface to thereby reduce said intensity of the radiation at said wave guide outlet;

one or more signal elements attached to the exterior surface of said wave guide on the outside of said radiation transmissive body, said signal elements being capable of reacting with said analyte to form analyte bound signal elements, said analyte bound signal elements providing

a differing degree of radiation escape through said exterior surface than said signal elements which are not bound to said analyte; and

a detector for measuring the change in radiation intensity at said wave guide outlet or the change in radiation escaping through the exterior surface of said wave guide to provide detection of said analyte that has reacted with said signal elements to form said analyte bound signal elements.

35. An assay system for detecting the presence of an analyte according to claim 34 wherein said signal elements are located at a given distance from said exterior surface and said analyte bound signal elements are tethered to said exterior surface to provide tethered signal elements which are located closer to said exterior surface than said signal elements which are not tethered thereto.

36. An assay system for detecting the presence of an analyte according to claim 35 wherein said signal element comprises:

a signal responsive moiety;

a spacer for attaching said signal responsive moiety to said exterior surface of said wave guide, said spacer having an end attached to said exterior surface and an end attached to said signal responsive moiety;

a first anchoring member having a first end attached to said exterior surface and a second end adapted to bind on a first site on a chosen analyte; and

a second anchoring member having a first end attached to said signal responsive moiety and a second end adapted to bind on a second site on said chosen analyte; and

the signal responsive moiety becoming tethered to said exterior surface only when said first and second anchoring members are bound to said chosen analyte.

37. An assay system for detecting the presence of and analyte according to claim 36 wherein said spacer is cleavable for releasably attaching said signal responsive moiety to said exterior surface, said cleavable spacer including a cleavage site intermediate the end of said spacer attached to said exterior surface and the end of said spacer attached to said signal responsive moiety, said signal responsive moiety remaining bound to said exterior surface after cleavage at said cleavage site only when said first and second anchoring members are bound to said chosen analyte.

38. An assay system for detecting the presence of an analyte according to claim 34 that includes a detector that is capable of identifying analyte bound signal elements.

39. An assay system for detecting the presence of an analyte according to claim 34 wherein said signal elements comprise:

a first signal element located in a first assay sector which is capable of reacting with a first chosen analyte to form a first bound analyte; and

a second signal element located in a second assay sector which is capable of reacting with a second chosen analyte to form a second bound analyte.

40. An assay system for detecting the presence of an analyte according to claim 34 wherein said wave guide is located in a disc.

41. An assay system for detecting the presence of an analyte according to claim 40 wherein said disc includes encoded computer software.

42. An assay system for detecting the presence of an analyte according to claim 41 wherein said disc is an optical disc.

43. An assay system for detecting the presence of an analyte according to claim 34 wherein said exterior surface is hydrophilic.

44. An assay device for use in detecting the presence of an analyte comprising:

a wave guide having a radiation inlet and a radiation outlet, said wave guide including an exterior surface defining a radiation transmissive body which extends between said inlet and said outlet such that radiation is transmitted radially through said body from said inlet to said outlet, a portion of said radially transmitted radiation escaping through said exterior surface; and

one or more signal elements attached to the exterior surface of said wave guide on the outside of said radiation transmissive body, said signal elements being capable of reacting with said analyte to form analyte bound signal elements, said analyte bound signal elements providing a differing degree of radiation escape through said exterior surface than said signal elements which are not bound to said analyte.

45. An assay device for detecting the presence of an analyte according to claim 44 wherein said signal element comprises:

a signal responsive moiety;

a spacer for attaching said signal responsive moiety to said exterior surface of said wave guide, said spacer having an end attached to said exterior surface and an end attached to said signal responsive moiety;

a first anchoring member having a first end attached to said exterior surface and a second end adapted to bind on a first site on a chosen analyte;

a second anchoring member having a first end attached to said signal responsive moiety and a second end adapted to bind on a second site on said chosen analyte; and

the signal responsive moiety becoming tethered to said exterior surface only when said first and second anchoring members are bound to said chosen analyte.

46. An assay device for detecting the presence of and analyte according to claim 45 wherein said spacer is cleavable for releasably attaching said signal responsive moiety to said exterior surface, said cleavable spacer including a cleavage site intermediate the end of said spacer attached to said exterior surface and the end of said spacer attached to said signal responsive moiety, said signal responsive moiety remaining bound to said exterior surface after cleavage at said cleavage site only when said first and second anchoring members are bound to said chosen analyte.

47. An assay device for detecting the presence of an analyte according to claim 44 wherein said wave guide is located in a disc.

48. An assay device for detecting the presence of an analyte according to claim 47 wherein said disc includes encoded computer software.

49. An assay device for detecting the presence of an analyte according to claim 48 wherein said disc is an optical disc.

50. An assay device for detecting the presence of an analyte according to claim 44 wherein said signal elements comprise:

a first signal element located in a first assay sector which is capable of reacting with a first chosen analyte to form a first bound analyte; and

a second signal element located in a second assay sector which is capable of reacting with a second chosen analyte to form a second bound analyte.

51. An assay device for detecting the presence of an analyte according to claim 45 wherein said exterior surface is hydrophilic.

52. A method for detecting the presence of an analyte comprising the steps of:

providing a wave guide having a radiation inlet and a radiation outlet, said wave guide including an exterior surface defining a radiation transmissive body which extends between said inlet and said outlet, said exterior surface allowing radiation to escape from said transmissive body, said wave guide including one or more signal elements attached to the exterior surface of said wave guide on the outside of said radiation transmissive body, said one or more signal elements being capable of reacting with said analyte to form one or more analyte bound signal elements, said analyte bound signal elements providing a differing degree of radiation escape through said exterior surface than said signal elements which are not bound to said analyte;

exposing said signal elements to a sample for a sufficient time to allow analyte in said sample to react with said one or more signal elements to form said analyte bound signal elements;

providing radiation of a given intensity to said wave guide inlet; and

measuring the intensity of radiation at said wave guide outlet or the intensity of radiation escaping through said exterior surface of said wave guide to provide detection of said analyte that has reacted with said signal elements to form said analyte bound signal elements.

53. A method for detecting the presence of an analyte according to claim 52 wherein wherein said signal elements are located at a given distance from said exterior surface and said analyte bound signal elements are tethered to said exterior surface to provide tethered signal elements which are located closer to said exterior surface than said signal elements which are not tethered thereto.

54. An method for detecting the presence of an analyte according to claim 53 wherein said signal element comprises:

a signal responsive moiety;

a spacer for attaching said signal responsive moiety to said exterior surface of said wave guide, said spacer having an end attached to said exterior surface and an end attached to said signal responsive moiety;

a first anchoring member having a first end attached to said exterior surface and a second end adapted to bind on a first site on a chosen analyte;

a second anchoring member having a first end attached to said signal responsive moiety and a second end adapted to bind on a second site on said chosen analyte; and

the signal responsive moiety becoming tethered to said exterior surface only when said first and second anchoring members are bound to said chosen analyte.

55. A method for detecting the presence of an analyte according to claim 54 wherein said spacer is cleavable for releasably attaching said signal responsive moiety to said exterior surface, said cleavable spacer including a cleavage site intermediate the end of said spacer attached to said exterior surface and the end of said spacer attached to said signal responsive moiety, said signal responsive moiety remaining bound to said exterior surface after cleavage at said cleavage site only when said first and second anchoring members are bound to said chosen analyte.

56. A method for detecting the presence of an analyte according to claim 52 which includes the further step of identifying which signal elements have become analyte bound signal elements.

57. A method for detecting the presence of an analyte according to claim 55 which includes the further step of identifying which signal elements have become analyte bound signal elements, said identification step including the step of removing signal elements from said exterior surface by cleaving said spacers at said cleavage sites so that only analyte bound signal elements remain attached to said exterior surface.

58. A non-specifc method for monitoring a sample for the presence of a plurality of analytes, said method comprising the steps of:

providing a wave guide having a radiation inlet and a radiation outlet, said wave guide including an exterior surface defining a radiation transmissive body which extends between said inlet and said outlet, said exterior surface allowing radiation to escape from said transmissive body, said wave guide including first and second signal elements attached to the exterior surface of said wave guide on the outside of said radiation transmissive body, said first and second signal elements being located in first and second assay sectors and being capable of reacting with first and second analytes to form first and second analyte bound signal elements, said first and second analyte bound signal elements providing a differing degree of radiation escape through said exterior surface than said signal elements which are not bound to said analyte;

continuously exposing said first and second signal elements to a sample to allow any first or second analyte in said sample to react with said first or second signal elements to form said first or second analyte bound signal elements;

providing radiation of a given intensity to said wave guide inlet; and

measuring the intensity of radiation at said wave guide outlet or the intensity of radiation escaping through said exterior surface of said wave guide to provide non- specific detection of said first analyte and/or said second analyte that has reacted with said signal elements to form said first and/or second analyte bound signal elements.

59. A specific method for monitoring a sample for the presence of a plurality of analytes, said method comprising the steps of non-specifically identifying the presence of an analyte in accordance with the method set forth in claim 58 and then specifically identifying the presence of a given analyte, said step of specifically identifying said analyte including removal of signal elements from said exterior surface which are not analyte bound signal elements.

60. A specific method for monitoring a sample for the presence of a plurality of analytes according to claim 59 wherein said signal element includes:

a signal responsive moiety;

a spacer for attaching said signal responsive moiety to said exterior surface of said wave guide, said spacer having an end attached to said exterior surface and an end attached to said signal responsive moiety, said spacer further including a cleavage site located between said end attached to said exterior surface and said end attached to said signal responsive moiety;

a first anchoring member having a first end attached to said exterior surface and a second end adapted to bind on a first site on said first or second analyte;

a second anchoring member having a first end attached to said signal responsive moiety and a second end adapted to bind on a second site on said first or second analyte; and

the signal responsive moiety becoming tethered to said exterior surface only when said first and second anchoring members are bound to said first or second analyte, said step of

removing signal elements from said exterior surface which are not analyte bound including the step of cleaving said spacers at said cleavage sites.

61. A radiation detector readable disk comprising a wave guide having a radiation inlet and a radiation outlet, said wave guide including a radiation transmission solid body of said disk which extends between said inlet and said outlet and an analyte detection surface on the exterior of said body.

62. The disk of claim 61 further comprising one or more signal elements attached to said surface.

63. The disk of claim 62 wherein said wave guide is provided such that a portion of radiation transmitted through said body from said inlet to said outlet escapes through said surface, said signal elements being capable of reacting with an analyte to form analyte bound signal elements, said analyte bound signal elements providing a differing degree of radiation escape through said surface than said signal elements which are not bound to an analyte.

64. The disk of claim 63 wherein said signal elements are located at a given distance from said surface and said analyte bound signal elements are tethered to said surface to provide tethered signal elements which are located closer to said surface than said signal elements which are not tethered thereto.

65. The disk of claim 63 wherein said signal element comprises:

a signal responsive moiety;

a spacer for attaching said signal responsive moiety to said surface of said wave guide, said spacer having an end attached to said surface and an end attached to said signal responsive moiety;

a first anchoring member having a first end attached to said surface and a second end adapted to bind on a first site on a chosen analyte;

a second anchoring member having a first end attached to said signal responsive moiety and a second end adapted to bind on a second site on said chosen analyte; and

the signal responsive moiety becoming tethered to said surface only when said first and second anchoring members are bound to said chosen analyte.

66. The disk of claim 65 wherein said spacer is cleavable for releasably attaching said signal responsive moiety to said surface, said cleavable spacer including a cleavage site intermediate the end of said spacer attached to said surface and the end of said spacer attached to said signal responsive moiety, said signal responsive moiety remaining bound to said surface after cleavage at said cleavage site only when said first and second anchoring members are bound to said chosen analyte.

67. The disk of claim 63 wherein one or more signal elements attached to the surface of said wave guide on the outside of said radiation transmissive body, said signal elements being capable of reacting with said analyte to form analyte bound signal elements, said analyte bound signal elements providing a differing degree of radiation escape through said surface than said signal elements which are not bound to said analyte.

68. The disk of any of claims 61 through 67 wherein said signal elements are provided in a spatially addressable pattern.

69. The disk of any one of claims 61 through 67 wherein said disk further comprises encoded software.

70. The disk of anyone one of claims 63 through 67 wherein said wave guide surface is provided as part of a chamber within said disk.

71. The disk of claim 68 when said disk further comprises software encoded in an area of said disk which is spatially distinct from the pattern of said elements.

72. An assay device comprising:

a substrate of a laser detector readable disk;

a wave guide located in said substrate and having a radiation inlet and a radiation outlet, said wave guide including a radiation transmitting body of said substrate which extends between said inlet and said outlet; and

said wave guide including an exterior surface such that radiation is transmitted through said body from said inlet to said outlet and a portion of said radiation escapes through said exterior surface;

73. The assay device of claim 72 further comprising a plurality of analyte binding elements attached to said substrate.

74. The assay device of claim 73 wherein said plurality of analyte binding elements are attached to said substrate in a spatially addressable pattern.

75. The assay device of any one of claims 72 through 74 wherein said disk further comprises computer software encoded upon said substrate.

76. The assay device of claim 74 wherein said disk further comprises computer software encoded upon said substrate in an area of said substrate which is spatially distinct from said spatially addressable pattern of said elements.

77. The assay device of claim 72 comprising:

one or more individual assay sectors segregated within said substrate; and

a sample inlet port associated with each of said one or more assay sectors.

78. The assay device of claim 77 wherein one or more analyte binding elements are provided within each of said one or more individual assay sectors.

79. The assay device of claim 78 wherein said one or more analyte binding elements include cleavable signal elements having a cleavable spacer and a signal responsive moiety.

80. The assay device of claim 75 wherein said software includes information for controlling the correct tracking of an incident laser.

REMARKS

It is requested that the within set of claims 34-80 be examined in this Divisional Application which is directed to the wave guide aspects of the present disclosure. The wave guide of applicant includes an optically transparent solid body portion of the optical disk which is used for transmission of light introduced at an inlet and which exits at an outlet. The radiation transmission body of the disk forming the wave guide allows radiation to escape at an exterior

surface of the wave guide, the assay sites being located at such surfaces. Signal elements are attached to an exterior surface of the wave guide which, when bound by an analyte, provide a differing degree of radiation escape through the exterior surface of the wave guide than do the signal elements which are not so bound.

A prior art wave guide structure is disclosed in WO 97/21090 which discloses a transverse spectroscopic detection chamber as shown schematically in Figure 16 of such disclosure. Light is reflected off of an inclined surface which passes through part of the disk body into a sample chamber provided for spectroscopic detection of a sample within the chamber and then exists from the chamber off of an inclined surface to a light collector. The reference puts the sample subject to the spectroscopic inspection within the chamber within the disk. In applicant, the signal elements to be inspected are placed on an exterior surface of the wave guide which can be an exterior surface of the disk or a surface within a chamber within the disk running alongside the wave guide. In applicant, changes in the radiation escaping laterally of the wave guide body past the signal elements is detected.

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